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|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
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| INFORMATION DISCLOSURE CITATION<br><i>(Use several sheets if necessary)</i> |  |  |   |   |   |   |   |   | ATTY. DOCKET NO. PC10664A     |         |  |      |       |       | SERIAL NO. 09/451,641 |            |             |                            |   |  |  |  |
|   |  |  |   |   |   |   |   |   | APPLICANT Danchen Gao, et al. |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  |  |   |   |   |   |   |   | FILING DATE November 30, 1999 |         |  |      |       |       |                       | GROUP 1618 |             |                            |   |  |  |  |
| U.S. PATENT DOCUMENTS   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
| EXAMINER INITIAL  |  | DOCUMENT NUMBER  |   |   |   |   |   |   |                               | DATE    |  | NAME |       | CLASS |                       | SUBCLASS   |             | FILING DATE IF APPROPRIATE |   |  |  |  |
|   |  | US   | 5 | 5 | 6 | 3 | 1 | 6 | 5                             | 10/8/96 | Talley, et al.   |      | 514   |       | 406                   |            |             |                            |   |  |  |  |
|   |  | US   | 6 | 2 | 3 | 2 | 4 | 2 | 2                             | 5/15/01 | Spitz, et al.  |      | 526   |       | 351                   |            |             |                            |   |  |  |  |
|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
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|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
| FOREIGN PATENT DOCUMENTS  |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
| DOCUMENT NUMBER   |  |  |   |   |   |   |   |   | DATE                          |         | COUNTRY  |      | CLASS |       | SUBCLASS              |            | TRANSLATION |                            |   |  |  |  |
|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            | YES NO      |                            |   |  |  |  |
|   |  | EP   | 0 | 4 | 8 | 8 | 8 | 5 | 6                             | 9/27/95 | Europe<br>(English language equivalent US Pat No. 6,232,422 cited above) |      | C01F  |       | 5/30                  |            |             |                            | X |  |  |  |
|   |  | WO   | 0 | 0 | 4 | 8 | 5 | 8 | 3                             | 8/24/00 | International  |      | A61P  |       | 25/06                 |            |             |                            |   |  |  |  |
|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
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|   |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)      |  |  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Vane, "Towards a better Aspirin", <i>Nature</i> , Vol. 367, pp. 215-216 (1994)   |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Battistini, et al., "COX-1 and COX-2: Toward the Development of More Selective NSAIDs", <i>Drug News and Perspectives</i> , Vol. 7, pp. 501-512 (1994)   |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Statutory Declaration of Professor Ian Tucker, dated January 4, 2003   |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Römpf Chemie Lexikon, 9. Auflage, Band 3, Georg Thieme Verlag, Stuttgart, 1990; pp. 2368-2370  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Teng, et al., "Formulation dependent pharmacokinetics, bioavailability and renal toxicity of a selective cyclooxygenase-1 inhibitor sc-560 in the rat", <i>J. Pharm. Pharmacol. Sci.</i> ( <a href="http://www.ualberta.ca/~cspis/">www.ualberta.ca/~cspis/</a> ), Vol. 6(2); pp. 205-210 (2003) |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |
|   |  | Stricklev, "Solubilizing Excipients in Oral and Injectable Formulations". <i>Pharmaceutical Research</i> . Vol. 21(2). pp. 201-230 (2004)  |   |   |   |   |   |   |                               |         |  |      |       |       |                       |            |             |                            |   |  |  |  |

| INFORMATION DISCLOSURE CITATION<br>(Use several sheets if necessary) |  |  | ATTY. DOCKET NO. PC10664A   | SERIAL NO. 09/451,641 |
|--|--|--|---|-----------------------|
|  |  |  | APPLICANT Danchen Gao, et al.   |                       |
|  |  |  | FILING DATE November 30, 1999   | GROUP 1618            |
|  |  |  | Waterbeemd, et al., "Estimation of Solubility, Permeability, Absorption and Bioavailability", <i>Drug Bioavailability</i> , Vol. 8, pp. 207-209   |                       |
|  |  |  | Davies, et al., "Clinical Pharmacokinetics and Pharmacodynamics of Celecoxib – A selective Cyclo-Coxygenase-2 Inhibitor", <i>Clin. Pharmacokinet</i> , Vol. 39(3); pp. 225-242 (2000)                                       |                       |
|  |  |  | Barnett International's Strategies for Improving Solubility, Practical Applications for Examining, Measuring, Predicting and Automating Solubility, June 2 – 4, 2004, Airport Marriott, Philadelphia, PA (6 pages)          |                       |
|  |  |  | 2004 PSG Technical Conference, Current Pharmaceutical Products, What Was Once Novel is Now Standard, Le Jardin, 8440 Highway 27, Woodbridge, Ontario October 26 – 27, 2004 (8 pages)  |                       |
|  |  |  | Memet Bahar, Experimental Protocol – Crystallization Experiments, Product: Celecoxib; Preparation Date: 03.09-3.09.2004 (5 pages)   |                       |
|  |  |  | Davies, et al., "Celecoxib: a new option in the treatment of arthropathies and familial adenomatous polyposis", <i>Expert Opinion on Pharmacotherapy</i> , Vol. 2(1); pp. 139-152 (2001)                                    |                       |
|  |  |  | Declaration of Neal M. Davies dated November 17, 2004   |                       |
|  |  |  | Declaration of Dr. Tambay Taskin dated February 8, 2006   |                       |
|  |  |  | Kesten, "Control and Optimisation of Cement Quality with Laser Diffraction Particle Size Analysis and Dry Dispersion, Sympatec GmbH, D-38678 Clausthal-Zellerfeld, Germany (1997)   |                       |
|  |  |  | Clinical Trial Protocol N49-95-02-006, dated September 6, 1995  |                       |
|  |  |  | Internal redacted Pfizer document dated July 26, 2007 re: particle size analysis of Arti X 200 mg tablets   |                       |
|  |  |  | Consultant Agreement re: Clinical Trial N49-95-02-006 dated September 20, 1995  |                       |
|  |  |  | Barber, et al., "A Logical Stepwise Approach to Laser Diffraction Particle Size Distribution Analysis Methods Development and Validation", <i>Pharmaceutical Development and Technology</i> , Vol. 3(2); pp. 153-161 (1998) |                       |
|  |  |  | Pharmaceutical Dosage Forms: Tablets, 2 <sup>nd</sup> Edition, Vol. 2, (1990)   |                       |
|  |  |  | Jennings, et al., "Particle size measurement: the equivalent spherical diameter", <i>Proc. R. Soc. Lond. A</i> , Vol. 419, pp. 137-149 (1988)   |                       |
|  |  |  | United States Provisional Patent Application No. 60/047,535, filed May 22, 1997.  |                       |
|  |  |  | Affidavit of Professor Shimon Benita, filed in support of the Opposition of Teva Pharmaceuticals, Ltd. And Trima Israeli Medical Products Maabarot Ltd. in Israel (date unknown)  |                       |
|  |  |  | Affidavit of Professor Shimon Benita in response to Affidavits submitted by G.D. Searle & Co. by Professor Jurgensen, Dr. Davis and Mr. Goren, filed in Israeli opposition (date unknown)                                   |                       |
|  |  |  | Opposition by the Pharmaceutical Industry Chamber of Bolivia dated October, 2000 (English translation)  |                       |
|  |  |  | Rejection by Republic of Colombia dated March 16, 2005 (English translation)  |                       |
|  |  |  | Rejection by Costa Rica dated approx. 2008, later overcome. (English translation)   |                       |
|  |  |  | Affidavit of Dr. Cynthia Webb filed on behalf of Teva Pharmaceutical Industries Ltd. And Trima Israeli Medical Products Ltd. In Israeli opposition (date unknown)   |                       |
|  |  |  | Affidavit of Professor Avraham Danon, filed on behalf of Teva Pharmaceutical Industries Ltd. And Trima Israeli Medical Products Ltd. In Israeli opposition (date unknown)   |                       |
|  |  |  | Affidavit of Professor Avraham Danon in response to Affidavits submitted by G.D. Searle & Co. by Professor Jurgensen, Dr. Davis and Mr. Goren, filed in Israeli opposition (date unknown)                                   |                       |

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|  |  |  | FILING DATE November 30, 1999   | GROUP 1618            |
|  |  |  | Opposition filed by Association of Pharmaceutical Laboratories in Ecuador dated August, 2000 (English Translation)  |                       |
|  |  |  | Decision by European Patent Office in Appeal No. T0696/05-3302 dated February 5, 2009   |                       |
|  |  |  | Opposition decision by European Patent Office regarding European Patent No. EP1049467 dated March 30, 2005  |                       |
|  |  |  | Notice of Opposition by Teva Pharmaceutical Industries Ltd. and supporting documents dated July 8, 2003 regarding European Patent No. EP1049467                     |                       |
|  |  |  | Opposition by Zentiva, k.s. in Estonia dated February 17, 2010 regarding Patent No. EE 04834  |                       |
|  |  |  | Opposition by Fako Ltd. in Eurasia regarding Eurasian Patent No. 3363 (English translation)   |                       |
|  |  |  | Affidavit of Neal M. Davies, Ph.D. dated March 2006, regarding Guatemalan Patent Application No. PI-990203 and US5,563,165  |                       |
|  |  |  | Final Decision filed in Guatemala ordering the Registry of Intellectual Property to proceed with respective registry regarding PI-1999-0203                         |                       |
|  |  |  | Rejection filed regarding Application No. PI-990203 in Guatemala dated June 16, 2003  |                       |
|  |  |  | Administrative Appeal Brief regarding Application No. PI-990203 in response to the Guatemalan Examiner's rejection of June 16, 2003                                 |                       |
|  |  |  | Submission in Guatemala dated April, 2004   |                       |
|  |  |  | Israel opposition summations, July 2006 (English translation)   |                       |
|  |  |  | Opposition Decision by Israel Patent Office dated February 28, 2008 (English translation)   |                       |
|  |  |  | Appeal to Set Aside Refusal of Application and Reconsideration to Grant Patent to Philippine AN:1-1999-02951 dated July 28, 2009                                    |                       |
|  |  |  | Notice of Appeal by Teva Pharmaceutical Industries Ltd. and Trima Israeli Medical Products Maabarot Ltd., filed in Israel, dated June 5, 2009 (English translation) |                       |
|  |  |  | Declaration by Neal M. Davies, Ph.D. dated November 10, 2004, filed in the Israel Opposition  |                       |
|  |  |  | Response to Statement filed by the Camara de la Industria Farmaceutica, in Venezuela regarding Venezuelan Patent Application No. 1999-002453                        |                       |
|  |  |  | Annulment Action filed in Peru on January 11, 2010  |                       |
|  |  |  | Appeal filed by Polpharma in Poland regarding Polish Patent No. PL 200957 BI (English Translation)  |                       |
|  |  |  | Appeal filed by Zentiva in Poland regarding the granting of Patent No.PL 200957 (English Translation)   |                       |
|  |  |  | Decision of Industrial Property Office of the Slovak Republic dated April 26, 2010 regarding Slovak Republic Patent No. SK 283510 (English translation)             |                       |
|  |  |  | Nullity Action filed by Zentiva in Slovak Republic on July 19, 2008 (English translation)   |                       |
|  |  |  | Opposition arguments by Teva Pharmaceuticals in Israel (date unknown) (English translation)   |                       |
|  |  |  | Turkish opposition summary by Fako Ilacleri A.S. (June 18, 2001) (English translation)  |                       |
|  |  |  | Turkish opposition by Professor. Levent Öner dated June 5, 2001 (English translation)   |                       |
|  |  |  | Turkish opposition by TÖM EKİP İLA, A.S. (2001) (English translation)   |                       |

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|  |  | FILING DATE November 30, 1999 |  | GROUP 1618            |  |  |
|  |  |                               | Turkish opposition by Nobel Ilac Sanayi Ve Ticaret, A.S. dated June 19, 2001 (English translation) |                       |  |  |
|  |  |                               | Turkish opposition statement by Fako Ilacлари dated June 18, 2001 (English translation)            |                       |  |  |
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| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |  |                               |  |                       |  |  |

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